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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|--|-------------|-----------------------|---------------------------------|------------------------|
| 10/627,439 | 07/25/2003 | Kenneth T. Richardson | 017380-000313US | 5370 |
| 20350 7590 07/24/2007 TOWNSEND AND TOWNSEND AND CREW, LLP TWO EMBARCADERO CENTER EIGHTH FLOOR SAN FRANCISCO, CA 94111-3834 | | | EXAMINER RAE, CHARLESWORTH E | |
| | | | ART UNIT 1614 | PAPER NUMBER |
| | | | MAIL DATE 07/24/2007 | DELIVERY MODE PAPER |

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/627,439

Applicant(s)

RICHARDSON ET AL.

Examiner

Charlesworth Rae

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 14 June 2007.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 29,30 and 49-69 is/are pending in the application.
- 4a) Of the above claim(s) 49-69 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 29-30 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date 6/14/07
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

DETAILED ACTION

Applicant's arguments, filed 6/14/07, have been fully considered but they are not deemed to be persuasive. Rejections and/or objections not reiterated from previous office actions are hereby withdrawn. The following rejections and/or objections are either reiterated or newly applied. They constitute the complete set of actions being applied to the instant application.

The new basis for the rejection under 103(a) is necessitated by the amendment. This action is therefore made final.

Status of the Claims

Claims 29-30, and 49-69 are currently pending in this application. Claims 49-69 are withdrawn as being directed to non-elected subject matter; claims 1-28 and 31-48 are cancelled.

Claims 29-30 are presented for examination.

Response to Arguments

Scope of Enablement rejection under 112, First Para.

Applicant contends that the specification expressly teaches how to make and administer the claimed layered tablet dosage form. Applicant further contends that the cited prior art [Richardson et al, (US Patent 6,207,190; Jones et al (US Patent 6,013,632); Fahim (US Patent 4,937,234)] fail to support the notion that the claimed embodiments cannot be made into a layered tablet dosage form or administered orally to a patient.

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Applicant's argument is not found to be persuasive because as specifically pointed out in the Office action (on pages 2-12), mailed 3/14/07, the invention encompasses layered tablet comprising an immediate-release layer and a sustained-release layer having synergistic anti-herpes viral activity (see specification, page 9, line 12 to page 10, line 8).

However, this rejection is rendered moot by applicant's amendment deleting the claim term "*for the treatment of herpes simplex and conditions giving rise thereto,*" previously recited in instant claims 29 and 30.

Rejection under 103(a)

Applicant contends that the instant claimed invention is unique and has unique benefits in clinical applications because of the following:

1) it permits patients who are physiologically unable to absorb clinically appropriate amounts of some active ingredients to do so when those elements are delivered in serial bolus amounts; diabetics and the elderly, for example, have irregular and frequently inadequate absorption of magnesium when delivered as a single dose.

2) magnesium oxide, for example, is included in the gastric, immediate-release section of the bi-layered tablet because magnesium oxide requires an acid environment to be converted into magnesium chloride, which is more useful and absorbable.

3) magnesium ascorbate and/or magnesium taurate are more effectively absorbed in the alkaline environment of the distal intestine and are therefore placed in the sustained-release section of the tablet.

4) distribution of different molecules between different parts of the intestine permits greater amounts of magnesium to be delivered without exceeding the maximum absorption capabilities of the gut and permits distribution of an active ingredient between two different chemical environments to take advantage of the different efficiencies of each component.

5) certain active ingredients, such as magnesium, zinc, and copper, compete for a limited intestinal capacity to absorb metals; if they are delivered simultaneously to the same region of the intestine, absorption rates for each are difficult to determine and quite hard to predict. Applicant asserts that the instant invention decreases the competition for absorption and raises the likelihood that desired amounts of each metal will enter the metabolic system.

6) magnesium and ascorbate operate synergistically against the herpes virus. Applicant asserts that the bilayer dosage form of the instant invention provides better confidence that adequate amounts of quercetin, whose absorption pattern is not well understood, will be present to act synergistically with either acyclovir or 5-ethyl-2'-deoxyuridine if these very commonly used antivirals are prescribed.

7) none of these effects are disclosed or suggested in any of the three cited references, either alone or in combination.

Applicant's arguments are not found to be persuasive because the above alleged special characteristics are not recited in the claims and the specification does not disclose any data to support the alleged superiority of the claimed invention, or unexpected results, as compared to the prior art. Applicant is invited to provide side by

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side comparative data to show the superiority/unexpected results of the instant claimed invention over the prior art.

Clearly, the cited prior art provides the suggestion/motivation for someone of skill in the art to combine the recited known ingredients to create the instant claimed invention.

Richardson et al. (US Patent 6,207,190) teach magnesium L-ascorbate, NAC, quercetin, selenium, L-cysteine, copper sulfate, and a bilayered tablet (col. 14, line 43 to col. 17, line 38; col. 22, lines 52-57). Instant claim 29 recites magnesium L-ascorbate, NAC, L-lysine monohydrochloride, quercetin, copper sulfate, and a bilayer tablet; instant claim 30 recites copper sulfate, quercetin, and a bilayer tablet. Richardson et al. teach compositions comprising magnesium salts or complexes e.g. magnesium taurate (col. 20, lines 46-51); instant claim 30 recites magnesium taurate. Richardson et al. teach compositions comprising either zinc salts or zinc complexes (col. 21, lines 11-17). Instant claim 29 recites the term "zinc picolinate," and instant claim 30 recites the term "zinc lysinate;" these terms are reasonably construed to be zinc salts or complexes. Richardson et al. teach L-selenomethionine (col. 21, lines 58-62); instant claims 29 and 30 recite L-selenomethionine. Richardson et al. teach that ascorbate may be present in the composition as ascorbic acid, metalloascorbate salts or complexes of ascorbate, or all of these (col. 21, lines 58-62). Instant claim 30 recites L-lysine ascorbate, which is reasonably construed as an ascorbate complex.

Murad (US Patent 5,804,594) teaches compositions comprising 2-amino-2-deoxy-D-glucose (D-glucosamine sulfate), NAC, quercetin, selenomethionine, zinc

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monomethionine, vitamin C, l-lysine, and copper sdebacate (col. 10, lines 35-66).

Instant claims 29 and 30 recite the term "*2-amino-2-deoxy-D-glucose*."

Fahim (US Patent 4,937,234) teaches that lysine, arginine and histidine are basic amino acids and might be used to neutralize the acidity of zinc salts (col. 1, line 66 to col. 2, liner 2); instant claim 29 recites the term "*l-lysine monohydrochloride*," while instant claim 30 recites the term "*l-lysine ascorbate*." Based on this teaching of Fahim, someone of skill in the art at the time the instant invention was made would have found it obvious to combine the teachings of Richardson et al., and Murad, and Fahim to created the instant claimed invention with a reasonable expectation of success.

This rejection is maintained for the reasons previously made of record in the Office action (pages 12-14), mailed 3/14/07, and the reasons delineated above.

Written Description rejection under 112, First Para.

This rejection is rendered moot by the amendment of the claims deleting the term "conditions giving rise thereto."

Nonstatutory Obviousness-Type Double Patenting rejection

This rejection is rendered moot by applicant's filing of the Terminal Disclaimer.

Claim rejections – 35 USC 103(a)

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 29 and 30 are rejected under USC 103(a) as being unpatentable over Richardson et al. (U.S. Patent 6,207,190; already made of record), and Murad (US Patent 5,804,594; already made of record), in view of Fahim (U.S. Patent 4, 937,234; already made of record).

The above discussion of the cited prior art under Response to Arguments in connection with the 103(a) rejection is incorporated by reference.

Thus, someone of skill in the art at the time the instant invention was made would have deemed it obvious to create the instant claimed invention with a reasonable expectation of success in view of the teaching of Richardson et al., and Murad, in view of Fahim.

Jones et al. (US Patent 6,013,632; already made of record) and Majeed et al. (US Patent 5,744,161; already made of record) are added to show the general state of the prior art.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Charlesworth Rae whose telephone number is 571-272-6029. The examiner can normally be reached between 9 a.m. to 5:30 p.m. Monday to Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ardin Marschel, can be reached at 571-272-0718. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR.

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Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have any questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 800-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

10 July 2007
CER

BRIAN-YONG S. KWON
PRIMARY EXAMINER

A handwritten signature in black ink, appearing to read 'B. Kwon', with a long horizontal flourish extending to the right.